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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/479,995	06/07/1995	ROBERT G. PERGOLIZZI	ENZ-(D1)(C2)	8797
28171	7590	05/27/2005	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/479,995

Applicant(s)

PERGOLIZZI ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/29/04, 5/28/04, 8/20/04, 9/2/04, & 11/30/04,
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) (See attached list) is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) (See attached list) is/are allowed.
6) ☒ Claim(s) (See attached list) is/are rejected.
7) ☒ Claim(s) (See attached list) is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Item # 4) on the enclosed PTO Form 326: Claims 283-362, 364-380, 382-398, 400-404, 406-439, 441-508, 510, 511, 516-525, and 527-549 are pending in the instant application.

Item # 5) on the enclosed PTO Form 326: Claims 283-362, 364, 365, 382, 383, 400, 401, 403, 404, 406, 407, 409-439, 441-505, 507, 508, 511, and 528-547 are allowed.

Item # 6) on the enclosed PTO Form 326: Claims 366-379, 384-398, 402, 408, 506, 510, 516-525, 527, 548, and 549 are rejected.

Item # 7) on the enclosed PTO Form 326: Claim 380 is objected to.

Applicant's arguments, filed 4/29/04, 5/28/04, 8/20/04, 9/2/04, and 11/30/04 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 366-379, 384-398, 402, 408, 510, 516-525, 527, 548, and 549 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

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description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 516-525, 527, 548, and 549 are newly rejected as necessitated by amendment due to their now containing NEW MATTER.

The combinations of segments as now set forth via amendment in independent claims 516 and 522 is NEW MATTER. Claims dependent directly or indirectly from claims 516 and 522 are also rejected hereinunder due to their dependence. Original claim 78 and those dependent therefrom, for example, lack the broad dinucleotide repeat or trinucleotide repeat limitation but rather only cite specific dinucleotide and mononucleotide polymer limitations. This broadening of repeat citation over said original claims is NEW MATTER. Consideration of the entirety of the instant disclosure as filed also has failed to reveal written support for said claims 516 or 522 embodiments.

Claim 510 is newly rejected as necessitated by amendment as now citing a hormonal receptor covalently attached to a polynucleotide sequence which has not been found in the entirety of the instant disclosure as filed and therefore is NEW MATTER. In REMARKS, filed 4/29/04, page 12, lines 22-23, of the specification is pointed to regarding support. Consideration of said page 12 citation reveals that the receptor recognized by its hormone is directed to an analyte of the instant invention and not the polynucleotide containing embodiment as now set forth in instant claim 510.

Applicants' REMARKS, filed 4/29/04, indicated that claim dependencies have been changed regarding claims 366, 370, 374-375, 379, 384, 388, 392-393, 397, 402, and 408. The newly submitted combination of these claims with their new dependencies have not been found as filed and therefore is NEW MATTER. This rejection is necessitated by amendment and is also directed to claims dependent therefrom due to their dependence.

VAGUENESS AND INDEFINITENESS

Claims 522-525, 527, and 549 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 522, lines 3-4, cites the phrase "said direct signal providing signal generating portion" which lacks antecedent basis due to no such "portion" being described previously in the claim. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 522 also contain this unclarity due to their dependence. This rejection is necessitated by amendment.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 516, 517, 520, and 521 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by MOLECULAR CLONING [Maniatis et al. (1982)].

Claim 516 has been amended to include embodiments wherein the claimed DNA molecule carries a polynucleotide sequence complementary to a gene of a nucleic-acid containing organism and a further repeating low-complexity polynucleotide sequence of a dinucleotide repeat. As previously cited in the previous office action, mailed 2/17/04, pages 51-54 of Maniatis et al. disclose filamentous phages which contain DNA molecules. Within this citation on page 53, the polylinker region includes repeating low-complexity CC segments as well as citing the presence of the β -galactosidase gene which is of bacterial origin as a nucleic acid containing organism thus continuing to support this rejection.

Claim 506 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Langer et al. [PNAS 78(11) 6633 (1981)].

This rejection is reiterated and maintained from the previous office action, mailed 2/17/04, due to biotin attachment to a polynucleotide sequence is covalent which thus supports a covalently attached characteristic when combined with antibody binding to said biotin.

The Declaration of Dr. Alex A. Waldrop, III, filed 9/2/04, is now only relevant to this rejection directed to instant claim 506 since the other claim 510 therein discussed is no longer rejected based on prior art. A reasonable summary of said Declaration is that antibody binding to a polynucleotide via biotin which has been attached to said polynucleotide results from both covalent bonding (polynucleotide to biotin) and noncovalent bonding (antibody to said biotin). These bondings are present as disclosed in Langer et al. as also summarized in said Declaration. Specifically covalent

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bonding is described in said Declaration in item # 13 on page 9. This admission supports this above prior art rejection based on Langer et al. It is acknowledged that several elements are present in the antibody-biotin-polynucleotide construct of Langer et al. including carbon atoms, oxygen atoms, covalent bonds, non-covalent bonds, etc. It is noted that instant claim 506 only requires that a polynucleotide is attached "covalently" to an antibody. This presence of a covalent bond between the biotin and polynucleotide is critical to attaching the antibody further thereto, as well as a noncovalent bond, and thus all limitations of instant claim 506 are met by elements within the Langer et al. reference construct, albeit other elements also being present in this embodiment within Langer et al. None of the discussions in said Declaration nor in instant claim 506 negate the above anticipatory correspondence between instant claim 506 and the disclosure of Langer et al.

INTERVIEW SUMMARY NOT AGREED WITH

In applicants' REMARKS, filed 8/20/04, on page 77, and reiterated on page 77 of their REMARKS, filed 11/30/04, applicants incorrectly indicated that the amendment to claim 510 was indicated by the Examiner as acceptable. No such acceptability statement was made. Rather, during the Interview the claim 510 amendment was discussed and noted by the Examiner as seeming to overcome the rejection discussed therewith, "but" that written basis for the amendment would be evaluated more fully in consideration of whatever actual amendment would be officially filed. It is noted that this consideration has revealed NEW MATTER in claim 510 as discussed above.

CLAIM OBJECTION

Claim 380 is objected to due to depending from a canceled claim.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 41.20(b) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment

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considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 25, 2005

 5/25/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER